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10/643,623	08/19/2003	Janos Szamosi	AM100224 P1	4463

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WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,623	SZAMOSI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-39* is/are pending in the application.

4a) Of the above claim(s) *15-31, 38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 08/18/08 is acknowledged.

Newly submitted claims 38 and 39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 38 and 39 present a tablet formulation that utilizes closed-ended "consisting of" language, which excludes additional ingredients not recited whereas the original invention utilizes open-ended "comprising" claim language and permits additional ingredients asides from those recited. Thus, the tablet formulation now presented in claims 38-39 represents a unique and distinct composition than that of the original invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-39 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has overcome the following rejection(s) by virtue of the amendment: (1) The 35 U.S.C. §103(a) rejection of claims 1, 5, 8-10 and 12 over Wehling *et al.* (US 5,178,878) in view of Mauger *et al.* (US 5,728,403) has been withdrawn; and (2) The 35 U.S.C. §103(a) rejection of claims 1, 5, 8 and 9 over Makino (US 5,501,861) has been withdrawnm

Claims 15-39 are pending in this action. Claims 32, 36 and 37 have been amended. New claims 38-39 have been added. Claims 15-31 have previously been withdrawn (based on non-elected invention). Claims 38-39 have been withdrawn herein (constructive election). Claims 1, 5, 8-10 and 12 have been cancelled herein. Claims 32-37 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (U.S. Pat. No. 5,576,014) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

Mizumoto *et al.* ('014) teach an intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

While Mizumoto *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Mizumoto *et al.* do not teach the selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglycercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which

consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Mizumoto *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an effective drug delivery tablet.

* * * * *

Claims 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu *et al.* (U.S. Patent No. 6,299,904).

Shimizu *et al.* ('904) teach a solid preparation, which is a tablet, having fast disintegration that comprises (i) a pharmaceutically active ingredient; (ii) one or more water-soluble sugar alcohols selected from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol and (iii) low-substituted hydroxypropycellulose (see Abstract); (col. 1, lines 8-57); (Claims 1 & 6).

Two or more water-soluble sugar alcohols can be used as a mixture in a given ratio (col. 4, line 66 – col. 5, line 2).

Lubricants are disclosed in the composition and include: sucrose fatty acid ester, polyethylene glycol, talc, stearic acid, etc. Polyethylene glycol can be used in an amount of 0.01 to 10 weight parts (col. 6, lines 26-34).

Additives are disclosed in the composition and include: artificial sweeteners such as aspartame, flavorants, lubricants, colorants, stabilizers, disintegrators, etc. (col. 5, line 59 – col. 6, line 25).

The tablets have a hardness of about 2 to about 20 kg (col. 8, lines 5-8). Applicant's recite a hardness of "less than about 2 kp", which nonetheless, would read on the "about 2 kp" taught by Shimizu.

Response to Arguments

Applicant's arguments filed 08/18/08 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §103(a) rejection over Wehling et al. ('878) in view of Mauger et al. ('403):**

Applicant argued, "This rejection is rendered moot as to claims 1, 5, 8-10 and 12, which have been cancelled with the current amendment."

This argument was found persuasive, by virtue of the amendment. Accordingly, this rejection has been withdrawn.

- **35 U.S.C. §103(a) rejection over Mizumoto et al. ('014) in view of Mauger et al. ('403):**

Applicant argued, "In contrast to Applicant's invention, Mizumoto neither suggests or teaches that a single saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities) or that a water soluble excipient in combination with a low melting point solid forms a fast dissolving granulation."

This argument was not persuasive since the instant "comprising" claim language permits the presence of additional components, asides from those recited, including the use of more than one saccharide disclosed by Mizumoto. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004). The tablets of Mizumoto comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). Thus, Mizumoto suggests that one saccharide may be used if desired. Furthermore, Applicant has not shown that the additional saccharide taught by Mizumoto would be detrimental to the formulation, when present. Moreover, Applicant's themselves demonstrate that the inclusion of two saccharides is permissible. Seven out of the eight examples disclosed by the Applicant utilize more than one saccharide. See for instance, Examples 1-7, all of which contain more than one saccharide. Thus, it cannot

be seen as to how the additional saccharide of Mizumoto would be adversary to the formulation.

Applicant argued, "Nowhere does Mizumoto teach that a saccharide and a low melting point compound may be combined in a granulation."

This was not deemed persuasive. Mizumoto clearly teaches sucrose fatty acid esters, polyethylene glycol, stearic acid and the like, which would read on the low melting point compounds claimed by Applicant. Mizumoto also discloses use of saccharides. The presence of both is permissible given the teachings of Mizumoto.

Applicant argued, "The listing of lubricants in Mizumoto is a general listing of optional lubricants. Of the lubricants listed in Mizumoto in col. 13, lines 50-65, magnesium stearate, talc and stearic acid have melting points substantially above 37°C."

This was not found convincing. As noted above, Mizumoto teaches lubricants, such as magnesium stearate. This lubricant would be considered a suitable and effective lubricant and would be a low melting point compound (i.e., melts below 37°C). Applicant's themselves include the use of magnesium stearate as shown for instance, in Examples 2 and 3 of the instant specification. Hence, it cannot be seen as to how the magnesium stearate of Mizumoto would not be a low melting point compound and would not provide for the same beneficial effects as those desired by Applicant.

Applicant argued, "The deficiencies of Mizumoto are not cured by Mauger. Mauger is directed to a taste masking coating not to a tablet that dissolves readily. Arguably Mauger does not even teach a fast dissolve coating much less a fast dissolving tablet."

These arguments were not persuasive. As previously stated, Mauger was relied upon to demonstrate the teaching that it is known to incorporate mixtures of mono-, di- and triglycerides, whereby the glycerides provide for aiding in taste-masking of drugs and enables a composition to melt at body temperature. The secondary reference thus teaches that mixtures of mono-, di- and triglycerides are well known and routinely used in the art. It is not necessary that the secondary reference teach each and every limitation of the claimed invention, but that it merely teaches and demonstrates the use of mixtures (of mono-, di- and triglycerides) in pharmaceutical formulations, such as tablets. The property argued by Applicant (fast dissolving) is insufficient to establish patentability of the claims as presently recited. Moreover, it is noted that the primary reference of Mizumoto amply teaches tablets that exhibit quick disintegration and dissolution and thus, meets this criteria.

- **35 U.S.C. §103(a) rejection over Makino ('861):**

Applicant argued, "Applicant argued, "This rejection is rendered moot as to claims 1, 5, 8 and 9, which have been cancelled with the current amendment."

This argument was found persuasive, by virtue of the amendment. Accordingly, this rejection has been withdrawn.

- **35 U.S.C. §103(a) rejection over Shimizu *et al.* ('904):**

Applicant argued, "Nowhere does Shimizu disclose or suggest the combination of a single saccharide and a low melting point compound to form a fast dissolving granulation comprising about 30% to about 75% of the tablet weight."

This argument was not deemed persuasive. Shimizu teaches a solid preparation – a tablet that has fast disintegration and that comprises a combination of an active ingredient, one or more water-soluble sugar alcohols as well as ingredients such as polyethylene glycol. The polyethylene glycol would be a suitable low melting point compound. With regards to the instant amounts of the fast dissolving granulation (about 30% to about 75% of the tablet weight), the Examiner points out that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The instant amounts claimed do not establish a patentable distinction over the explicit teachings of the art, which recognizes and teaches the same ingredients employed by Applicant and used for the same field of endeavor.

Applicant argued, "The hardness range claimed by Applicants is substantially lower than the range of 2-20 kg of Shimizu. Tablet hardness may impact a number of properties of a tablet, including processability, robustness and dissolution behavior."

This argument was not persuasive. The instant hardness of "about 1.7 kP" does not distinguish over the hardness range disclosed by Shimizu (2-20 kg), which would also be considered a suitable hardness level. Applicant's argument regarding properties affected by hardness was not persuasive. The prior art teaches a combination of the same elements provided in a similar fashion as that instantly claimed, and thus, it would be expected that the properties imparted by those elements would also be the same as that sought by Applicant. "[T]he discovery of a previously unappreciated property of a prior

art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 15-31 drawn to an invention nonelected with traverse in the reply filed on 11/09/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

December 05, 2008